REMARKS

Applicants have amended claims 5, 75, and 77. Upon entry of the amendments, claims 5, 7, 8, and 75-79 will be pending. Applicants request entry of the amendments and reconsideration of the claims.

Applicants gratefully acknowledge the withdrawal of the rejection of claims 5, 7, and 8 under 35 U.S.C. § 103 as being unpatentable over Howard, et al. in view of Bliel et al. and further in view of Russell-Jones, G.J.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 5, 8, 75, 77, and 79 stand rejected under 35 U.S.C. § 112 second paragraph.

In particular, the Examiner asserts that claims 5, 75, and 77 recite the broad range "comprising an antigen or antibody, and further comprising a mucosal targeting protein." The Examiner also asserts that the claims recite a narrower range "comprising ZP3 and *E. coli* enterotoxin subunit B." The Examiner concludes that the claims are indefinite because it is not clear whether the narrower range is merely exemplary or if it is a required feature of the claims.

In addition, the Examiner states that the use of "further comprising" is confusing because it appears that the claims encompass a homogenate of a plant expressing ZP3 and *E. coli* enterotoxin subunit B in addition to expressing an antigen or antibody and a mucosal targeting protein.

Applicants respectfully traverse the rejection. Without acquiescing to the rejection and solely to expedite the prosecution of the application, Applicants have amended claims 5, 75, and 77 by deleting the objected-to phrase "further comprising an antigen or antibody."

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections Under 35 U.S.C. § 103(a)

Claims 5, 7, 8, and 75-79 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard et al. (WO 97/10347) in view of Bliel et al. (WO 98/00440), Russell-Jones, G.J. (J. of Controlled Release (2000) vol. 65; pp. 49-54), and Mowat et al. (Immunology Letters (1999) vol. 65; pp. 133-40).

The Examiner asserts that Howard et al. teach: (1) the production of vaccines in transgenic plants; (2) the oral administration of plant seed and the use of transgenic plant seed as a feed composition; (3) combining transgenic plants, plant organs, and seeds to yield a homogenate; (4) animal feed in combination with an immunogenic composition comprising the recombinant antigen; (5) plants that have set seed and are placed in a holding area mature and dry down; (6) compositions further comprising an adjuvant; (7) adjuvants as pharmaceutically acceptable carriers; and (8) agrobacterium-mediated transformation to introduce a transgene into a plant chromosome for chromosomal expression without a viral intermediate. The Examiner admits that Howard et al. do not teach any one of an immunocontraceptive protein, a mucosal targeting protein, and a saponin adjuvant.

The Examiner alleges that the deficiencies of Howard et al. can be found in Bliel et al., Russell-Jones, and Mowat et al. and that the combination of references renders the claimed invention obvious. In particular, the Examiner finds that Bleil et al. teach (1) immunocontraceptive vaccines that are orally administered in bait or feed formulations and (2) the ZP3 protein from mouse sperm which is species specific for mice. The Examiner also states that Russell-Jones teaches mucosal binding proteins as carriers for oral vaccine delivery and specifically mentions the oral contraceptive protein ZP3. Finally, the Examiner asserts that Mowat et al. teach the saponin adjuvant Quil A for use with orally-administered vaccines.

The Examiner claims that at the time of invention, it would have been obvious to modify the transgenic plants taught by Howard et al. to express an immunocontraceptive, such as those taught by Bliel et al., and that one would have been motivated to do so because Bliel et al. teach that oral contraceptive vaccines are cost effective and lack side effects. Additionally, the Examiner alleges that a person of skill in the art would have a reasonable expectation of success given the success of Howard et al. in producing a TGEV vaccine. Further, the Examiner states that one would have been motivated to utilize a mucosal binding protein as a carrier for an oral vaccine based on the teachings of Russell-Jones. Finally, the Examiner asserts that it would have been obvious to use the saponin adjuvant of Mowat et al. because of the teaching of Mowat et al. that the immune response to a vaccine is significantly elevated when a saponin adjuvant is used.

Applicants respectfully traverse the rejection.

Howard et al. teaches expressing an antigen in a transgenic plant to generate a vaccine. Additionally, Howard et al. teaches collecting transgenic plant material and mixing the material with animal feed and introducing the vaccine to animals through the plant/feed mixture. Finally, Howard et al. also teaches using agrobacterium-mediated transformation to prepare the transgenic plants. Bliel et al. teaches orally available immunocontraceptive vaccines that can be delivered using bait or feed. Russell-Jones teaches using mucosal binding proteins as carriers for orally available vaccines. Mowat et al. teaches using the saponin, Quil A, as an adjuvant for an orally available vaccine.

Applicants submit that the Examiner has failed to carry the burden of establishing a *prima facie* case of obviousness. Specifically, the Examiner has failed to demonstrate a motivation to combine the references to derive the claimed invention. For example, the Examiner finds motivation to combine the teaching of Bleil et al. with Howard et al. based on the recitation of Bleil et al. that oral contraceptive vaccines are cost effective and lack side effects. However, Bleil et el. do not teach or suggest an orally administered vaccine derived using transgenic plant technology methods but rather oral vaccines generated by traditional technologies. Therefore, Bleil et al. does not teach or suggest that an orally administered vaccine generated using completely distinct methods, that is, recombinant plant technology methods, is either cost effective or lacks side effects. Further, the mere fact that Bleil et al. suggests that oral vaccines produced by traditional methods are cost effective is not a motivation to make oral vaccines using transgenic plant technology methods.

Furthermore, Applicants respectfully assert that the Examiner's stated motivation for combining Russell-Jones and Howard et al. that "one would have been motivated to utilize a mucosal binding protein as a carrier for an oral vaccine and one would expect this mucosal binding protein to increase the immune response to the orally-delivered vaccine" is a conclusory statement. The Examiner failed to point out why one would have been motivated to utilize a mucosal binding protein as a carrier for an oral vaccine.

Applicants also submit that the Examiner's *prima facie* case fails because Howard et al. does not teach a "stable dry homogenate of a transgenic plant" as required by claims 5, 8, 75, 77 and 79. Applicants also submit that the Examiner's *prima facie* case fails because Howard et al. does not teach a "stable dry homogenate comprising a dehydrated transgenic plant material" as required by claims 7, 8,76, 78 and 79. The Examiner asserts that combining transgenic plants, plant organs, and seeds into animal feed is equivalent to the production of a homogenate. However, one of skill in the art would understand that the combination of transgenic plants, plant organs, seeds, and animal feed, taught by Howard et al. is not a stable dry homogenate of a transgenic plant, but rather is merely a mixture of transgenic plant material and feed. One of skill in the art would understand that a mixture of transgenic plant material and one or more additional components is clearly not a stable dry homogenate as required by the instant claims.

In conclusion, Howard et al. does not teach or suggest a "stable dry homogenate of a transgenic plant" or a "stable dry homogenate comprising a dehydrated transgenic plant", as required by the instant claims, and none of Bleil et al., Russell-Jones, and Mowat et al. either alone or in combination cure this deficiency.

In addition, the Examiner asserts that a "stable dry homogenate" is taught in Example 2 of Howard et al. which describes the production of first generation transgenic plants by drying mature plants in a greenhouse prior to harvesting seed. According to Example 2, drying was done to harvest viable seed stock for the future propagation of the next generation of transgenic plants and not for the production of a stable dry homogenate. Applicants submit that the plant seeds in Example 2 of Howard are clearly not a stable dry homogenate of transgenic plant material. Further, there is no teaching or suggestion that the first generation seeds of Howard are either mixed with feed or homogenized.

In view of all of the above, Applicants respectfully request reconsideration and withdrawal of the rejections.

Amendment and cancellation of the claims herein are not to be construed as an acquiescence to any of the rejections/objections made in the instant Office Action or in any previous Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the claims as originally filed, or substantially similar claims in one or more subsequent patent applications.

For at least the foregoing reasons, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. Should any of the claims not be found to be in condition for allowance, the Examiner is requested to call Applicant's undersigned representative to discuss the application. Applicant thanks the Examiner in advance for this courtesy.

The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No.

2002(203121). In view of the foregoing, Applicants request reconsideration and allowance of the pending claims.

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Respectfully submitted,

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